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*ADMITTED IN NY & NJ

January 17, 2022

BY ECF & EMAIL

The Honorable Mary Kay Vyskocil
United States District Court
Southern District of New York
500 Pearl Street
New York, New York 10007

Re: *United States v. Navarro, et al,* 20 CR 160
Seth Fishman – Defendant

Your Honor:

I write in response to the Government's supplemental proffer in which it seeks to admit certain records from the Delaware State Division of Professional Regulations' investigation of the defendants Fishman and Giannelli in connection with the death of the racehorse, Louisville.

I also write in the expectation that, at tomorrow's pretrial conference, the Court will hear further argument with regard to the appropriate limitations on opinion testimony by the Government's experts.

For the reasons set forth in this letter and in our earlier *in limine* motion, the Court should (1) adhere to its original ruling and preclude evidence regarding the death of the racehorse, Louisville; and (2) preclude expert testimony by the Government's witnesses regarding the "safety and efficacy" of the defendant's products.

I. The Court Should Adhere To Its Original Ruling And Preclude Evidence Regarding The Death Of The Racehorse, Louisville

In the Government's original proffer, it seeks to offer records from the Delaware investigation:

> To establish Fishman and Giannelli's knowledge of the allegations in the Complaint, their intent to defraud and mislead that particular state regulator, their

> knowledge (or conscious avoidance of confirmation) of the Food, Drug, and Cosmetic Act's ("FDCA") application to the drugs peddled through their efforts, and to contextualize the false statements made by Fishman and Giannelli to the investigators both in their recorded interviews and their statement.

(Gov't MIL at p. 31).

At the January 13, 2022, pretrial conference, the Court issued a preliminary ruling to the effect that, while evidence relating to the investigation could be introduced, it must be redacted to eliminate reference to the death of the racehorse.

In a letter dated January 14, 2022, the Government supplements the grounds for admission of evidence regarding the death of the horse, to add:

> [evidence of the death] is more probative than prejudicial given the findings the jury must make regarding: (1) whether these and similar drugs were adulterated, *i.e.*, unsafe, *see* 21 U.S.C. § 351(a)(5) (a drug is deemed adulterated "if it is a new animal drug which is unsafe" within the meaning of the FDCA, 21 U.S.C. § 351(a)(5)); and (2) the defendants' state of mind in distributing injectable drugs to lay person without a prescription or supervision.

(Gov't 1/14/22 Letter at p. 1)

First, as the Government rightly notes, a new animal drug's safety under the FDCA depends on its "general reputation in the scientific community." That is a black and white threshold question with a simple yes or no answer. Unless the scientific community generally recognizes a particular drug as safe and effective for its intended uses, the drug is deemed unsafe as a matter of law – and thus adulterated – absent FDA approval. (21 U.S.C. §§ 351(a)(5), 360(b)). Thus, evidence of the death of any individual animal does not provide further evidence that the drug allegedly sold by Dr. Fishman was "unsafe." The only discernable purpose for this additional evidence is to smear the defendants as horse killers.

Secondly, the racehorse suffered a fatal attack – likely from the inter-arterial administration of the injectable product – adds nothing of relevance with regard to the state of mind of these defendants. As the prosecutors urged in Court, the fact and nature of the Delaware investigation put the defendants on notice that certain authorities considered some of their activities suspect. It was on that basis that the Court rules preliminarily to admit those items of proof. The fact that the horse suffered a fatal attack adds nothing to the relevant inferences that could be drawn regarding the defendants' collective state of mind. Again, piling Louisville's demise on top of that heap would serve only to demonize the defendants as death merchants.

Because the Government offers no persuasive reason to revisit the prior exclusionary ruling, the Court should adhere to it.

II. The Court Should Preclude Opinion Testimony By The Government's Expert Witnesses Regarding The "Safety and Efficacy" Of Dr. Fishman's Products

The fact that the FDCA's regulatory regime contains its own definition of "new animal drug;" and, deems these products to be "unsafe" when the method of testing the product, applying for regulatory approval, manufacturing the product, and distributing it, fails to comport with statutory requirements, bears upon the appropriate limitations on experts testimony.

In our initial Motion *in limine* we expressly sought to preclude opinion evidence regarding the "safety and efficacy" of Dr. Fishman's products. (Defense MIL at p.11). As we argued in that submission, at the end of the case, the jury will be instructed regarding the elements of the adulteration and misbranding statute which is at the core of this prosecution. Moreover, throughout the trial the jury will be admonished to "follow the law." Under these circumstances, opinion evidence regarding the chemical content of Dr. Fishman's products, and the likely effect of these ingredients upon the health and welfare of a racehorse is not essential to a finding as to whether or not the Government has met its burden of proof. Moreover, it would open the door to a battle of competing views as to whether or not these products were dangerous to animals or marked a substantial improvement upon those products – including FDA approved products – in common circulation among owners and trainers.

On January 10, 2022, the Government provided defense counsel with a substantial additional trove of 3500 material. Included was material regarding the subject matter of proposed testimony by each of the Government's three proffered experts.

The 3500 material for Cynthia Cole, DVM, is particularly concerning to defense counsel. It is apparent from an examination of the 3500 material that the Government intends to lead Dr. Cole through each item on the defendant's product list and to obtain opinion testimony regarding precisely the matters set forth above. (Annexed hereto as an Exhibit is GX-3504-15 which clearly demonstrates the Government's intent to elicit just this kind of testimony). Should the Court permit Dr. Cole to testify to her review of products listed in the Equestology catalogue, and to offer her opinion regarding the "safety and efficacy" of each of these products, it will "open the door" to a distracting battle of expert witnesses that may include testimony by Dr. Fishman himself regarding research and findings concerning the attributes of those products Dr. Fishman distributed both in the United States and abroad. This testimony would be enormously time-consuming, would lead the jury far astray from the issues in the case, and would contravene the Court's asserted interest in having the jury confine its deliberations to the elements of the crime charged.[1]

[1] Lest the Government argue that while the Court should permit its expert witnesses to testify regarding the "safety and efficacy" of Dr. Fishman's products, but should preclude the defense from calling its own experts or eliciting rebuttal evidence on this issue, it is worthy of note that while the Government began interviewing Dr. Cole in June of 2020, those items of 3500 material which clearly evidence the scope of the doctor's likely testimony were provided to defense counsel on January 10, 2022 – long after the deadline for Expert Witness Notice. It would be a denial of due process for the Court to permit opinion testimony regarding the safety and efficacy of Dr. Fishman's products – on the one hand – while precluding rebuttal testimony on this very subject – on the other.

Accordingly, at the pretrial conference, we will ask the Court to set parameters on expert testimony by each of the Government's three expert witnesses in order to avoid this kind of unfairness.

Conclusion

For the reasons set forth in this letter and in our earlier *in limine* motion, the Court should (1) preclude evidence regarding the death of the racehorse, Louisville; and (2) preclude expert testimony by the Government's witnesses regarding the "safety and efficacy" of the defendant's products.

Most respectfully,

/s/ Maurice H. Sercarz

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